

**REMARKS**

Applicants have herein amended claims 74, 76, 78-81, 88, 90, and 99-112. The amendments to claims 76, 78-81, 88, and 99-112 involve merely formatting changes, mostly necessitated by the amendments to independent claims 74 and 90. Thus, these amendments do not raise any issue of new matter. Support for the amendments to claim 74 may be found in the specification at paragraphs 12, 14, 31, 37, 64 and 65, and support for the amendments to claim 90 may be found in the specification at paragraphs 12, 15, 31, 34, 37, 64 and 65. Thus, applicants maintain that these amendments do not present new matter. Accordingly, applicants respectfully request that the Examiner enter this Amendment. Upon entry of this Amendment, claims 74-112, as amended, will be pending and under examination.

**Claim Rejections under 35 U.S.C. §103(a)**

The Examiner rejected claims 74-112 under 35 U.S.C. §103(a) as allegedly unpatentable over Fishbein (U.S. Patent No. 6,576,659). The Examiner stated that Fishbein teaches the treatment of wounds in general, with an effective amount of oxandrolone, and that the preferred effective amount disclosed by Fishbein encompasses the preferred amounts taught in the present application. The Examiner acknowledged that Fishbein does not specifically teach the preferred dosage or the specific instances of wound treatment as claimed. However, the Examiner asserted that it would have been obvious to one of ordinary skill in the art at the time of the invention to treat wounds utilizing the claimed dosages because Fishbein teaches the treatment of wounds utilizing oxandrolone in general, and it is well established that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

In response, without conceding the correctness of the Examiner's position, applicants note that the claims, as amended herein, are directed to methods for treating a human patient having a wound in need of treatment comprising systemically or topically administering to the patient a therapeutically effective amount of an anabolic steroid which promotes wound healing.

The anabolic steroid employed in the claimed methods must have the functional properties of (a) increasing at least two-fold the expression of type I and/or type III procollagen by human fibroblasts cultured in the presence of collagen, and (b) not increasing the expression of type I and/or type III procollagen by human fibroblasts cultured in the presence of plastic. Thus, the now pending claims do not relate to a method of treatment comprising administration of oxandrolone *per se*, as taught by Fishbein, but instead relate to the administration of an anabolic steroid exhibiting the specified functional characteristics.

Applicants maintain that the specification provides an enabling disclosure of the methods now claimed. In this regard, applicants note that the specification teaches a quantitative assay for determining whether an anabolic steroid of interest increases the expression of type I and/or type III procollagen by human fibroblasts cultured in the presence of collagen, but does not increase the expression of type I and/or type III procollagen by human fibroblasts cultured in the presence of plastic. See paragraphs 35-38 and 61-65 (Example 2). Moreover, the specification provides a working example of an anabolic steroid (oxandrolone) that increases the expression of type I and type III procollagen 2- and 11-fold, respectively, by human fibroblasts cultured in the presence of collagen, but does not increase the expression of type I or type III procollagen by human fibroblasts cultured in the presence of plastic. See paragraphs 64 and 65. Although Federal Circuit “precedent does hold that disclosure of one or two species *may* not enable a broad genus,” the Court has held that a single example of an embodiment of an invention may suffice to show enablement provided that “any gaps between the disclosures and the claim breadth could be easily bridged.” *Amgen v. Hoechst* 314 F.3d 1313, 1336 (Fed. Cir. 2003) (emphasis in original). Applicants maintain that in the instant application, the disclosure of oxandrolone as an example of a compound that satisfies the functional requirements of the wound-healing anabolic steroid recited in the pending claims suffices to show enablement of the claims. Accordingly, applicants respectfully submit that the Examiner’s grounds of rejection have been rendered moot by the claim amendments presented herein.


**Conclusion**

In view of the remarks presented hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the obviousness rejections set forth in the January 25, 2006 Final Office Action, and earnestly solicit allowance of all claims now pending in the subject application. If a telephone interview would be of assistance in expediting prosecution of the subject application, the Examiner is invited to telephone the undersigned at the number provided below.

Authorization is hereby given to charge any fees necessary for the filing of the present Amendment to Deposit Account No. 11-0600.

Respectfully submitted,  
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